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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,042

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Sudhanshu Vratl

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

07/01/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,042	<b>Applicant(s)</b> VRATI, SUDHANSHU	
	<b>Examiner</b> AGNIESZKA BOESEN	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 1020.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-27 and 30-49 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 and 34-49 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 is/are allowed.
- 6) ☒ Claim(s) 24-27 and 30-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The Amendment filed April 2, 2010 in response to the Office Action of October 2, 2010 is acknowledged and has been entered. Claims 24, 34 and 35 have been amended. Claims 21-23, and 34-49 are withdrawn. Claims 28-29 have been canceled. Rejections of canceled claims are moot. Claims 24-27, and 30-33 are under examination in this Office action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of Claims 24-27 and 30-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is maintained**.

Applicant's arguments have been fully considered but fail to persuade. Applicant disagrees that the deposit of RadEs is required in order to enable the claims. Applicant amended the claims to incorporate the method steps regarding making the recombinant adenovirus RAdEs. Applicant submitted the copy of the notification from European Collection of Cell Cultures (ECACC) showing that RadEs has been accepted as a patent deposit in accordance with the Budapest Treaty of 1977 on December 17, 2004.

In response the Examiner acknowledges that the method steps recited in claim 24 guide the skilled artisan how to make the recombinant adenovirus (RAdEs) of the present invention comprising the cDNA encoding the JEV E secretory protein (Es) incorporated into replication incompetent ( $\Delta$ E1/ $\Delta$ E3) human adenovirus type 5 (Ad5) genome –RAd, however the method steps do not recite any specific SEQ ID NO: which are comprised in the very specific

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recombinant adenovirus deposited under Accession number 0412101. The skilled artisan following the method steps recited in claim 24 would make a large number of recombinant adenoviruses comprising known variants of JEV E secretory protein (Es), however the skilled artisan may not necessarily arrive at the specific variant such as the one deposited under ECACC Accession Number 0412101. The skilled artisan would be required to conduct undue amount experimentation in order to obtain the very specific recombinant adenovirus deposited under ECACC Accession Number 0412101. Because Applicant's claims recite the ECACC Accession Number 0412101 the claims necessarily require that the skilled artisan must obtain the recombinant adenovirus deposited under Accession Number 0412101, and not just any variant of the recombinant adenovirus encoding the JEV E secretory protein (Es).

The copy of the notification from European Collection of Cell Cultures (ECACC) regarding the ECACC Accession Number 0412101 is acknowledged however Applicant is also required to submit an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

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(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Amendment to the claims to recite specific SEQ ID NO: used in making the recombinant adenovirus would help overcome the present rejection. OR Amendment to the claims to delete the ECACC Accession Number 0412101 would help overcome the present rejection. Applicant is also invited to point out to the specific SEQ ID NOs required to make the ECACC Accession Number 0412101 in the specification.

**Rejection of Claims 24-27 and 30-32 under 35 U.S.C. 112, first paragraph**, because the specification, while being enabling for an **immunogenic composition** comprising the recombinant adenovirus RAdEs, does not reasonably provide enablement for the recombinant adenovirus RAdEs **vaccine, is maintained**.

Applicant's arguments have been fully considered but fail to persuade. Applicant provided a copy of definition of vaccine from medical dictionaries. Applicant argues that the present specification describes that the present vaccine improved immunity against JEV and therefore the claims should be enabled.

In response to Applicant's arguments the Examiner acknowledges that various types of vaccine, including therapeutic and prophylactic exist in the art. However neither Applicant's

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specification nor the present claims define the claimed vaccine as a therapeutic or prophylactic vaccine. Applicant's specification contemplates that the claimed vaccine should confer protection against JEV infection in humans. While Applicant's specification shows that protection of mice against Japanese encephalitis virus can be achieved by immunization with the claimed recombinant adenovirus RAdEs, Applicant's specification does not provide evidence that immunization of humans with the recombinant adenovirus RAdEs provides protection against infection with the Japanese encephalitis virus. Applicant's specification discloses that the RAdEs induced high titers of JEV neutralizing antibodies which protected the immunized mice against lethal JEV challenge. The specification provides working examples where mice were immunized intramuscular (IM) and orally with RAdEs. Oral route of virus delivery induced low titers of anti-JEV antibodies that had only little JEV neutralizing activity. IM immunizations with both RAdEa and RAdEs resulted in high titers of anti-JEV antibodies. RAdEa induced very low titers of JEV neutralizing antibodies whereas RAdEs inoculation resulted in high titers of JEV neutralizing antibodies. Splenocytes from mice immunized IM with RAdEs secreted large amounts of interferon- $\gamma$  and moderate amounts of interleukin-5. These splenocytes also showed cytotoxic activity against JEV-infected cells. Mice immunized IM with RAdEs showed complete protection against the lethal dose of JEV given intra-cerebral (Example 10-14). FIG. 4 shows Antibody response in mice. BALB/c mice were immunized with RAdEa, RAdEs or with the vaccine by IM or oral route of inoculation. The specification does not show working examples which provide evidence that immunization of humans with the claimed vaccine confers protection against JEV infection. The art teaches that the vaccine against Japanese encephalitis does currently exist however the existing vaccine is a whole virus vaccine, while the claimed

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vaccine which is based on the recombinant adenovirus. Despite numerous studies showing protection in animals against various viruses induced by immunization with adenoviral vectors carrying viral antigens such as HIV, HCV, HBV and other viruses, a protective adenoviral based vaccine against HIV, HCV, HBV or other viruses does not currently exist (see Tatsis, Molecular Therapy, Volume 10, 2004).

In order to establish that the claimed recombinant adenovirus RAdE can provide protection against the Japanese encephalitis in humans, the skilled artisan would be required to conduct undue experimentation. Thus in view of the foregoing the rejection is maintained.

***Claim Rejections - 35 USC § 103***

Rejection of Claims 24-27 and 30-32 under 35 U.S.C. 103(a) as being unpatentable over Kaur et al. (Journal of Infectious Diseases, 2001, p. 1-12 in IDS of 6/30/2008) in view of Jaiswal et al. (Journal of Virology, December 2003, p. 12907-12913 in IDS of 6/30/2008) **is withdrawn**.

Examiner notes that if Applicant amends the claims to recite enabled embodiments, the art rejection of record may be reinstated.

***Conclusion***

SEQ ID NO: 1 is free of prior art of record.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/  
Examiner, Art Unit 1648

/Stacy B Chen/  
Primary Examiner, Art Unit 1648

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